would be a real possibility. The result would clearly be in violation of the policy and spirit of the patent laws and against the public interest.

The need for a more detailed specification of issues and standards in the MAC regulation is more than a matter of sound administrative policy. It is, as well, a necessary element of fair procedure designed to insure that persons affected are not deprived of substantial rights. A supplier whose brand is priced above the MAC level may be exposed to substantial economic injury. Even if a drug supplier has no "right" to have its drugs accepted in a governmental reimbursement program, "that [does not] mean that the government can act arbitrarily, either substantively or procedurally", against the supplier.[47/] An individual or corporation which has a business relationship with the government is "entitled to have notice of the standards and procedures which regulate these relationships".[48/]

In the context of a proceeding that may have a substantial impact upon a drug supplier's business, the supplier should have "full and precise notice" of the kinds of evidence that will be relevant to upholding its position.[49/] In the case of a MAC determination, effective notice is possible only if the standards are spelled out with greater clarity than is now the case. Unless this is done, it would be impossible to develop a record enabling the Board to discharge its obligation to take "a hard look at the issues with the use of reasons and standards".[50/] Without an articulation of governing standards, HEW will not be acting in accordance with the requirements of basic fairness.[51/]